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October 26, 2007

Janet Schulueter  
Division Director  
Division of Material Safety and State Agreements  
United States Nuclear Regulatory Commission  
Washington, D.C. 20555-0001

Re: Proposed Interim Enforcement Policy for Neutron and  
Accelerator Irradiated Gemstones

Dear Director Schulueter:

I am writing on behalf of jewelry industry representatives and  
other stakeholders in the trade of importing and distributing  
neutron and accelerator irradiated gemstones.<sup>1</sup>

Based on the low impacts to public health and safety and the  
environment in the handling of irradiated gemstones, and  
because the cost and timeliness of obtaining specific licenses for  
the entire jewelry industry will be burdensome and disruptive to  
both the NRC and the jewelry industry, the JVC requests that the  
NRC develop and issue an interim enforcement policy addressing  
two subjects:

1. The exercise of NRC enforcement discretion  
regarding the inventory of nuclear irradiated  
gemstones (primarily blue topaz) currently in the  
United States, and
2. The exercise of NRC enforcement discretion for  
importers of accelerator irradiated gemstones during  
the implementation period for the final rule on the  
expanded definition of byproduct material.

<sup>1</sup> The Jewelers Vigilance Committee is a trade association dedicated to the  
promotion of integrity in the jewelry industry through legal compliance. Our  
nearly 10,000 members from every sector of the trade are committed to legal  
compliance and the promotion of high business standards for the  
manufacture and sale of all jewelry products in the United States.

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### Introduction

On July 26, 2007 representative of our industry met with various members of NRC staff in your offices at Rockville, Md. The subject of that meeting was industry compliance with the long standing NRC licensing requirements for distribution of exempt concentrations of byproduct material. The future rules covering accelerator irradiated materials were also included on the agenda.

During the meeting, industry representatives acknowledged the history of difficulties related to compliance by our industry with licensing provisions covering the importation, possession and distribution of nuclear irradiated gemstones. We pledged to work diligently to achieve full compliance in the shortest possible time frame. A path forward was devised, which included filing applications for appropriate licensing with the NRC and providing information to the NRC on the levels of radiation present in our gemstones. This included providing records of past testing, and well as making representative inventories available for NRC testing in order to confirm the lack of any impact on public health and safety. At a meeting in New York on August 2, 2007, thousands of carats of neutron irradiated gemstones were made available to NRC and other officials for testing. Since that date, the NRC has tested inventories of irradiated gemstones around the country consisting of thousand of carats of material. According to the NRC, no public health and safety risks have been detected from this gemstone material.

The meeting on July 26 also covered the new rules on accelerator irradiated gemstones. At the meeting, the industry was informed that these regulations would similarly apply to accelerator irradiated gemstones, and would require importation, possession and distribution licenses. While the final regulations provide a transition period (either 6 or 12 months) for entities to acquire licenses for possession and distribution of this material, no such transition period is provided to acquire an importation license. All gemstone material that is accelerator irradiated offered for sale in the United States is imported.

### Current inventory of blue topaz

Dealers in blue topaz acknowledge the history of difficulties related to compliance by our industry with licensing provisions

covering the importation, possession and distribution of nuclear irradiated gemstones. They have cooperated with the NRC by providing inventories to be tested, applying for appropriate licensing and by providing records of past testing of the material, all of which indicate no threat to public health and safety, as has been acknowledge in press reports by the NRC itself.

These dealers are experiencing a severe interruption of trade in this product since their inventory already in the US is not in full compliance and, without some form of official guidance from the NRC, cannot be distributed. Millions of carats of this material have been admitted into the US through Customs every year, and sold by dealers and retailers while there have been no enforcement actions of any kind. The many US dealers and retailers now in possession of millions of carats of the material therefore seek guidance from the NRC in the exercise of their enforcement discretion, as to the disposition of this inventory. The publication of an interim enforcement policy would allow them to sell off this inventory while the NRC and the industry moves towards full compliance. This includes processing the applications for the five applicants for the appropriate importation, possession and distribution licenses. Thus, moving forward, the industry would be soon be in full compliance and will have minimized the economic harm arising from the circumstances while at the same time ensuring protection of the public health and safety.

In light of the above, we attach a proposed interim enforcement guidance that, if adopted by the NRC, would permit dealers to disposition current inventories of blue topaz while ensuring protection of the public health and safety.

The industry will continue to work with the NRC to address compliance with NRC licensing regulations, and to address long term issues pertaining to standards for radiation levels for irradiated gemstones. However, the immediate concerns pertaining to current inventories must be addressed in the short term to avoid any further economic harm to the gemstone industry.

This would also obviate the need for gemstone distributors with current inventory to immediately apply for NRC or Agreement

States licenses, which would be unnecessarily burdensome for both the dealers and the regulators.

#### Accelerator irradiated gemstones

The industry acknowledges that the regulations issued on October 1, 2007 will apply to the possession and distribution of accelerator irradiated gemstones. While there is a transition period provided for entities that seek to possess and distribute this material, there is no such transition period applicable to those seeking to become licensed to import this material.

Currently, all accelerator irradiated gemstones are imported. While there are currently applicants for appropriate licensing, there are not any entities in the US currently holding NRC licenses to import accelerator irradiated gemstones. Thus, until one or more of the current applicants becomes fully licensed under the new rules, there is no lawful way to import accelerator-irradiated gemstones that could allow continued domestic exempt distribution during the transition period. This again presents the possibility of a severe interruption in the trade of accelerator irradiated gemstones. Significantly, the NRC has provided a mechanism to issue a general license to import byproduct material to entities that have obtained a license to possess such materials from the NRC or an Agreement State. This set of circumstances would require an importer to obtain a specific license to import material, which would only be necessary for a short period of time or until the dealer came into compliance with the newly-promulgated regulation by the end of the implementation period (i.e., a holder of a possession license would automatically fall under the general import license and no specific license would be required). Thus, some guidance is needed during this interim period to ensure a smooth transition to the new regulatory program.

Because of the nature of this material and the circumstances of the accelerator, the potential public health and safety and common defense and security issues of this gem material are de minimis. The industry will continue to cooperate with the NRC to confirm that this is indeed the case.

In light of the above, we attach a draft of a proposed interim enforcement policy that would ensure public health and safety, reduce the resource impact on the NRC by providing a transition period in which the jewelry industry could apply for the necessary licenses, and present a less severe interruption in trade.

We appreciate the level of cooperation that has been established between the NRC and the gem industry throughout this process. We hope that issuance of an enforcement guidance memorandum will facilitate the work being done by the NRC and the industry to complete the process of full compliance.

Thank you for your concern and attention. We look forward to your prompt response.

Very truly yours,

A handwritten signature in black ink, reading "Cecilia L. Gardner". The signature is fluid and cursive, with a long horizontal stroke at the end.

Cecilia L. Gardner  
President and CEO, General Counsel  
Jewelers Vigilance Committee

Enclosure

## **INTERIM ENFORCEMENT POLICY NEUTRON AND ACCELERATOR IRRADIATED GEMSTONES**

### A. Interim Enforcement Policies for Exempt Distribution License Requirements pursuant to 10 CFR 30.70

#### Current inventory of neutron irradiated blue topaz

This section sets forth the interim enforcement policy that the NRC will follow to exercise enforcement discretion for certain violations of requirements in 10 CFR 30.70 for the possession and distribution of neutron irradiated gemstones. It addresses violations associated with persons possessing and seeking to distribute unlicensed gem material in the United States. The NRC has conducted tests on inventories of irradiated gemstones around the country consisting of thousand of carats of material. Based on the results of those tests, the NRC has determined that permitting possession and distribution of neutron-irradiated gemstones will not endanger the public health and safety or common defense and security. Moreover, were the NRC to require every gemstone dealer to obtain a license in order to disposition current inventories, the sheer number of licensing requests would create further delay in achieving full compliance with regulatory requirements. Moreover, it would divert limited NRC resources from licensing and regulating other material with more significant impacts on the public health and safety and common defense and security.

#### **Exercise of Enforcement Discretion**

Based on the NRC's extensive investigation of inventories of blue topaz currently present in the United States to determine the risk, if any, to public health and safety, and in order to provide guidance for sellers of this product, the NRC will allow sales of blue topaz under the following conditions:

1. Suppliers of neutron irradiated blue topaz must be able to demonstrate, if requested, that the inventory to be sold has been present in the US for a period of no less than six months;
2. Suppliers of neutron irradiated blue topaz must be able to demonstrate, if requested, that the inventory to be sold has been adequately tested using readily available technology to ensure that no measurable radiation is detected when compared with background levels of radiation.<sup>1</sup>

<sup>1</sup>

The jewelry industry and NRC will work together to develop minimum technical guidance documents to support implementation of this interim enforcement policy.

3. Suppliers of neutron irradiated blue topaz must be able to provide, if requested, the identities of suppliers from whom such inventory to be sold were acquired.

NRC will continue to exercise enforcement discretion in these cases until either: (A) NRC amends its regulations to create a new general license for gemstones, exempts the material from the regulation, or decides to not pursue a new regulation; (B) the facility makes a timely request for and thereafter obtains a specific possession license from the NRC or an Agreement State and a distribution license from the NRC; or (C) the facility ceases operations.

### Exceptions

Enforcement action may be taken where there is (a) failure to respond and provide the information required by the notice and response program as outlined above; or (b) failure to provide complete and accurate information to the NRC. Enforcement sanctions in these cases may include civil penalties as well as Orders to modify or revoke the authority to possess or distribute neutron irradiated gemstones.

### B. Interim Enforcement Policies for the Transition Plan for the Expanded Definition of Byproduct Material

#### Transition period for importation of accelerator irradiated gemstones

This section sets for the interim enforcement policy that the NRC will follow to exercise enforcement discretion for certain violations of requirements in 10 CFR 110.5 for the importation of material pursuant to the expanded definition of byproduct material, including accelerator irradiated gemstones. It addresses violations by persons or entities that import accelerator irradiated gemstones in the absence of a general or specific license during the implementation period for the new regulations on the expanded definition of byproduct material.

The final rule allows an additional 6-month period from the effective date of the final rule to apply for a license amendment for those entities that current hold a license to possess neutron-irradiated material; and an additional 12-month period from the effective date of the final rule to apply for a new license if one is needed. Under 10 CFR 110.27, a general license is issued to any person to import byproduct material if the consignee is authorized to possess the material under an NRC or Agreement State license. During the implementation period, however, there is no requirement that person possessing byproduct material have obtained an NRC or Agreement State license. As a result, importers of accelerator-irradiated material would need to apply for and receive a

specific import license under 10 CFR 110.31 even though they are not required to have a possession license during this period. This dynamic would create the same set of circumstances that the implementation period was designed to avoid (e.g., disrupt supplies, overwhelm NRC and Agreement States licensing capabilities, etc.) and would not result in any incremental protection of the public health and safety or the common defense and security.

Consequently, based on the expectation of relatively low impacts to public health and safety and the environment from accelerator-irradiated gemstones, and because NRC recognizes that the cost of obtaining a specific license can be burdensome, the NRC has decided to exercise its enforcement discretion provided that the conditions discussed below are satisfied.

#### Exercise of Enforcement Discretion

Under this interim enforcement policy, based on the low risk, if any, to public health and safety and the common defense and security from the importation of accelerator-irradiated materials, and in order to provide guidance for importers of these products, the NRC will allow the import of accelerator-irradiated gemstones during the implementation period for the final rule on the expanded definition of byproduct material under the following conditions:

1. Importers of accelerator-irradiated gemstones must be able to demonstrate, if requested, that the inventory to be sold has been adequately tested using readily available technology to ensure that no measurable radiation is detected when compared with background levels of radiation.
2. Importers of accelerator-irradiated gemstones must be able to provide, if requested, the identities of suppliers from whom such inventory to be sold were acquired.

NRC will continue to exercise enforcement discretion in these cases until either: (A) NRC amends its regulations to create a new general license for gemstones, exempts the material from the regulation, or decides to not pursue a new regulation; (B) the facility makes a timely request for and thereafter obtains a specific license to possess the material from the NRC or an Agreement State; or (C) the facility ceases operations.

#### Exceptions

Enforcement action may be taken where there is (a) failure to respond and provide the information required by the notice and response program as



outlined above; or (b) failure to provide complete and accurate information to the NRC. Enforcement sanctions in these cases may include civil penalties as well as Orders to modify or revoke the authority to import accelerator-irradiated gemstones.